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| U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTORNEY'S DOCKET NUMBER 1581.1120000/RWE/FRC |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5 To Be Assigned 10/505137 |
| INTERNATIONAL APPLICATION NO. PCT/GB03/00702 | INTERNATIONAL FILING DATE 19 February 2003 (19-02-2003) | PRIORITY DATE CLAIMED 19 February 2002 (19-02-2002) |
| TITLE OF INVENTION SOLVENT-BASED STERILISATION OF PHARMACEUTICALS | | |
| APPLICANT(S) FOR DO/EO/US Parveen BHATARAH and Alan Kenneth GREENWOOD | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| <p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). </p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ul style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). </p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. </p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A preliminary amendment.</p> <p>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information: <ul style="list-style-type: none"> 1) Authorization to Treat Reply as Incorporating an Extension of Time under 37 C.F.R. 1.136(a)(3); 2) Copy of Pub. Int'l. Appl. No. PCT/GB03/00702 (Int'l. Pub. No. WO 03/070285 A1) along with Article 19 Amendment and Int'l. Search Report; 3) Copy of International Preliminary Examination Report (IPER); and 4) Two (2) return postcards. </p> | | |

| U.S. APPLICATION NO. 107505137 To be assigned | INTERNATIONAL APPLICATION NO. PCT/GB03/00702 | ATTORNEY'S DOCKET NUMBER 1581.1120000/RWE/FRC | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--------------------------------------|--------------|------|--------------|--------|----|-----------|--------------------|------|---|-----------|--|--|--|------------|--|--|--|--------------------------------------|-------------|
| 21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. \$1080.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$920.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$770.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$730.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 | | CALCULATIONS PTO USE ONLY | | | | | | | | | | | | | | | | | | | | |
| ENTER APPROPRIATE BASIC FEE AMOUNT = | | \$ 920.00 | | | | | | | | | | | | | | | | | | | | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | \$ | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">CLAIMS</th> <th style="width: 25%;">NUMBER FILED</th> <th style="width: 25%;">NUMBER EXTRA</th> <th style="width: 25%;">RATE</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>30 -20</td> <td>10</td> <td>x \$18.00</td> </tr> <tr> <td>Independent claims</td> <td>3 -3</td> <td>0</td> <td>x \$86.00</td> </tr> <tr> <td colspan="2">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td></td> <td>+ \$290.00</td> </tr> <tr> <td colspan="2"></td> <td></td> <td style="text-align: right;">TOTAL OF ABOVE CALCULATIONS =</td> </tr> </tbody> </table> | | CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | Total claims | 30 -20 | 10 | x \$18.00 | Independent claims | 3 -3 | 0 | x \$86.00 | MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | + \$290.00 | | | | TOTAL OF ABOVE CALCULATIONS = | \$ 1,100.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | | | | | | | | | | | | | | | | | | |
| Total claims | 30 -20 | 10 | x \$18.00 | | | | | | | | | | | | | | | | | | | |
| Independent claims | 3 -3 | 0 | x \$86.00 | | | | | | | | | | | | | | | | | | | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | + \$290.00 | | | | | | | | | | | | | | | | | | | |
| | | | TOTAL OF ABOVE CALCULATIONS = | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. | | \$ | | | | | | | | | | | | | | | | | | | | |
| SUBTOTAL = | | \$ 1,100.00 | | | | | | | | | | | | | | | | | | | | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | \$ | | | | | | | | | | | | | | | | | | | | |
| TOTAL NATIONAL FEE = | | \$ 1,100.00 | | | | | | | | | | | | | | | | | | | | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | \$ | | | | | | | | | | | | | | | | | | | | |
| TOTAL FEES ENCLOSED = | | \$ 1,100.00 | | | | | | | | | | | | | | | | | | | | |
| | | Amount to be refunded: \$ | | | | | | | | | | | | | | | | | | | | |
| | | charged: \$ 1,100.00 | | | | | | | | | | | | | | | | | | | | |
| a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-0036</u> . A duplicate copy of this sheet is enclosed. d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | | | | | | | | | | | | | | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status. | | | | | | | | | | | | | | | | | | | | | | |
| SEND ALL CORRESPONDENCE TO: CUSTOMER NUMBER 26111 Sterne, Kessler, Goldstein & Fox P.L.L.C. | | | | | | | | | | | | | | | | | | | | | | |
| SIGNATURE  NAME Frank R. Cottingham | | AUG. 19, 2004 | | | | | | | | | | | | | | | | | | | | |
| REGISTRATION NUMBER 50437 | | | | | | | | | | | | | | | | | | | | | | |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bhatarah *et al.*

Appl. No.: To be assigned

(U.S. National Phase of PCT/GB03/00702)

Int'l. Filing Date: 19 February 2003

For: **Solvent-Based Sterilisation of
Pharmaceuticals**

Confirmation No.: To be assigned

Art Unit: To be assigned

Examiner: To be assigned

Atty. Docket: 1581.1120000/RWE/FRC

**Authorization to Treat a Reply as Incorporating an
Extension of Time Under 37 C.F.R. § 1.136(a)(3)**

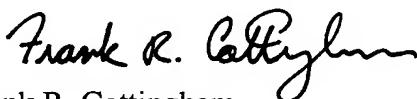
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: AUG. 19, 2004

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